

the results of any reviews and evaluations conducted under paragraph (b)(1)(iii) or paragraph (b)(3) of this section which, in the opinion of the Board, indicate noncompliance with these rules or OPTN policies, or indicate a risk to the health of patients or to the public safety, and shall provide any recommendations for appropriate action by the Secretary. Appropriate action may include removal of designation as a transplant program under § 121.9, termination of a transplant hospital's participation in Medicare or Medicaid, termination of a transplant hospital's reimbursement under Medicare and Medicaid, termination of an OPO's reimbursement under Medicare and Medicaid, if the noncompliance is with a policy designated by the Secretary as covered by section 1138 of the Social Security Act, or such other compliance or enforcement measures contained in policies developed under § 121.4.

(2) *Secretary's action on recommendations.* Upon the Secretary's review of the Board of Directors' recommendations, the Secretary may:

- (i) Request further information from the Board of Directors or the alleged violator, or both;
- (ii) Decline to accept the recommendation;
- (iii) Accept the recommendation, and notify the alleged violator of the Secretary's decision; or
- (iv) Take such other action as the Secretary deems necessary.

[63 FR 16332, Apr. 2, 1998, as amended at 64 FR 56661, Oct. 20, 1999]

§ 121.11 Record maintenance and reporting requirements.

(a) *Record maintenance.* Records shall be maintained and made available subject to OPTN policies and applicable limitations based on personal privacy as follows:

(1) The OPTN and the Scientific Registry, as appropriate, shall:

- (i) Maintain and operate an automated system for managing information about transplant candidates, transplant recipients, and organ donors, including a computerized list of individuals waiting for transplants;

- (ii) Maintain records of all transplant candidates, all organ donors and all transplant recipients;

- (iii) Operate, maintain, receive, publish, and transmit such records and information electronically, to the extent feasible, except when hard copy is requested; and

- (iv) In making information available, provide manuals, forms, flow charts, operating instructions, or other explanatory materials as necessary to understand, interpret, and use the information accurately and efficiently.

(2) *Organ procurement organizations and transplant programs—(i) Maintenance of records.* All OPOs and transplant programs shall maintain such records pertaining to each potential donor identified, each organ retrieved, each recipient transplanted and such other transplantation-related matters as the Secretary deems necessary to carry out her/his responsibilities under the Act. The OPO or transplant program shall maintain these records for seven years.

(ii) *Access to facilities and records.* OPOs and transplant hospitals shall permit the Secretary and the Comptroller General, or their designees, to inspect facilities and records pertaining to any aspect of services performed related to organ donation and transplantation.

(b) *Reporting requirements.* (1) The OPTN and the Scientific Registry, as appropriate, shall:

- (i) In addition to special reports which the Secretary may require, submit to the Secretary a report not less than once every fiscal year on a schedule prescribed by the Secretary. The report shall include the following information in a form prescribed by the Secretary:

- (A) Information that the Secretary prescribes as necessary to assess the effectiveness of the Nation's organ donation, procurement and transplantation system;

- (B) Information that the Secretary deems necessary for the report to Congress required by Section 376 of the Act; and,

- (C) Any other information that the Secretary prescribes.

(ii) Provide to the Scientific Registry data on transplant candidates and recipients, and other information that the Secretary deems appropriate. The information shall be provided in the form and on the schedule prescribed by the Secretary;

(iii) Provide to the Secretary any data that the Secretary requests;

(iv) Make available to the public timely and accurate program-specific information on the performance of transplant programs. This shall include free dissemination over the Internet, and shall be presented, explained, and organized as necessary to understand, interpret, and use the information accurately and efficiently. These data shall be updated no less frequently than every six months (or such longer period as the Secretary determines would provide more useful information to patients, their families, and their physicians), and shall include risk-adjusted probabilities of receiving a transplant or dying while awaiting a transplant, risk-adjusted graft and patient survival following the transplant, and risk-adjusted overall survival following listing for such intervals as the Secretary shall prescribe. These data shall include confidence intervals or other measures that provide information on the extent to which chance may influence transplant program-specific results. Such data shall also include such other cost or performance information as the Secretary may specify, including but not limited to transplant program-specific information on waiting time within medical status, organ wastage, and refusal of organ offers. These data shall also be presented no more than six months later than the period to which they apply;

(v) Respond to reasonable requests from the public for data needed for bona fide research or analysis purposes, to the extent that the OPTN's or Scientific Registry's resources permit, or as directed by the Secretary. The OPTN or the Scientific Registry may impose reasonable charges for the separable costs of responding to such requests. Patient-identified data may be made available to bona fide researchers upon a showing that the research design requires such data for matching or

other purposes, and that appropriate confidentiality protections, including destruction of patient identifiers upon completion of matching, will be followed. All requests shall be processed expeditiously, with data normally made available within 30 days from the date of request;

(vi) Respond to reasonable requests from the public for data needed to assess the performance of the OPTN or Scientific Registry, to assess individual transplant programs, or for other purposes. The OPTN or Scientific Registry may impose charges for the separable costs of responding to such requests. An estimate of such charges shall be provided to the requester before processing the request. All requests should be processed expeditiously, with data normally made available within 30 days from the date of request; and

(vii) Provide data to an OPTN member, without charge, that has been assembled, stored, or transformed from data originally supplied by that member.

(2) An organ procurement organization or transplant hospital shall, as specified from time to time by the Secretary, submit to the OPTN, to the Scientific Registry, as appropriate, and to the Secretary information regarding transplantation candidates, transplant recipients, donors of organs, transplant program costs and performance, and other information that the Secretary deems appropriate. Such information shall be in the form required and shall be submitted in accordance with the schedule prescribed. No restrictions on subsequent redisclosure may be imposed by any organ procurement organization or transplant hospital.

(c) *Public access to data.* The Secretary may release to the public information collected under this section when the Secretary determines that the public interest will be served by such release. The information which may be released includes, but is not limited to, information on the comparative costs and patient outcomes at each transplant program affiliated with the OPTN, transplant program personnel, information regarding instances in which transplant programs

refuse offers of organs to their patients, information regarding characteristics of individual transplant programs, information regarding waiting time at individual transplant programs, and such other data as the Secretary determines will provide information to patients, their families, and their physicians that will assist them in making decisions regarding transplantation.

[63 FR 16332, Apr. 2, 1998, as amended at 64 FR 56661, Oct. 20, 1999]

§ 121.12 Advisory Committee on Organ Transplantation.

The Secretary will establish, consistent with the Federal Advisory Committee Act, the Advisory Committee on Organ Transplantation. The Secretary may seek the comments of the Advisory Committee on proposed OPTN policies and such other matters as the Secretary determines.

[64 FR 56661, Oct. 20, 1999]

§ 121.13 Definition of human organ under section 301 of the National Organ Transplant Act of 1984, as amended.

Human organ, as covered by section 301 of the National Organ Transplant Act of 1984, as amended, means the human (including fetal) kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, skin, intestine (including the esophagus, stomach, small and/or large intestine, or any portion of the gastrointestinal tract) or any vascularized composite allograft defined in §121.2. It also means any subpart thereof, including that derived from a fetus.

[78 FR 40042, July 3, 2013]

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